Environment Canada Environnement Canada
20351141 VOL ISS 7 840618
EXC # 001

<REPORT> CC

OOFF

SUMMARY

of Notification Requirements in New Chemicals Legislation in OECD Member States

a) - Executive Summary
b) - EEC Member States
c) - Non-EEC Member States

by

Peter Strahlendorf

Prepared under contract to the Commercial Chemicals Branch, Environmental Protection Service, Environment Canada.

CC-7
June 18, 1984

Box 625, Stn. Q
Toronto, M4T 2N4
(416) 481-7088

SUMMARY

OF NOTIFICATION REQUIREMENTS IN

NEW CHEMICALS LEGISLATION IN

OECD MEMBER STATES

BY

PETER STRAHLENDORF
CONSULTING AND RESEARCH
BOX 625, Station Q
Toronto, Ontario
M4T 2N4

This report has not undergone detailed technical review by the Environmental Protection Service and the content does not necessarily reflect the views and policies of Environment Canada.

This unedited version is undergoing a limited distribution to transfer the information to people working in related studies. This distribution is not intended to signify publication and, if the report is referenced, the author should cite it as an unpublished report of the Branch indicated below.

Any comments concerning its content should be directed to:

Commercial Chemicals Branch
Environmental Protection Programs Directorate
Environmental Protectoin Service
Environment Canada
Ottawa, Ontario
K1A 1C8

CC-7
June 18, 1984

SUMMARY
of Notification Requirements in New Chemicals Legislation in OECD Member States

by

Peter Strahlendorf

Prepared under contract to the Commercial Chemicals Branch, Environmental Protection Service, Environment Canada.

June 18, 1984

Box 625, Stn. Q
Toronto, M4T 2N4
(416) 481-7088

SUMMARY
of Notification Requirements in New Chemicals Legislation in OECD Member States

The following is a summary of the more significant issues in chemical control in the area of notification requirements for new chemicals. It is based on the legislative and administrative experience in OECD Member States.

Scope

No country has an omnibus statute covering all potentially harmful chemicals. Most countries exclude from new chemicals legislation chemicals covered by existing legislation (eg: pesticides, pharmaceuticals). Some countries require notification only for trade in poisons (eg: Switzerland, N.Z.), not new chemicals in general. Such legislation is "antiquated" in comparison with the objectives of the Sixth Amendment, TSCA and the OECD chemical program. A common approach is to define a notifiable chemical substance in broad terms followed by specific exemptions, rather than listing specific chemicals or classes requiring notification (eg: Sweden). The wording differs but most define chemical substances to include elements and compounds. TSCA refers to radicals and the Sixth Amendment refers to additives. An important question is whether to include mixtures, preparations, formulations or products in the definition. Alternatively, a new chemical in a preparation may be notifiable as opposed to the preparation itself. A subsequent careful distinction must be made whether testing is required of the new chemical in the preparation or the preparation itself.

Inventory

An important element in any scheme is the mechanism whereby "new" chemicals are distinguished from "old" or non-notifiable chemicals. Countries which regulate trade in poisons have poison lists and notification is required if the chemical is on the list, but this begs the question of evaluating new chemicals, whether poisons or not. One mechanism is to chose a date; chemicals on the market prior to that date are "old" non-notifiable chemicals. Certainty and fairness to industry can only be accomplished by publishing an inventory of chemicals marketed before that date (eg: ECOIN). An important question is whether the inventory is enlarged over time as new chemicals are marketed. Such new chemicals are added to the inventory and become "old" non-notifiable chemicals (eg: U.S.). In contradiction, a static list (EINECS) means that "once new always new" - if the chemical is not on the inventory it is still a new notifiable chemical no matter how many times others have notified it. This wastefulness can be alleviated by, for example (EEC), a 10 year exemption - if the chemical was notified at least ten years ago, it need not be notified even though it is not on the inventory. The major systems allow a chemical identity to be encoded on the inventory, but some mechanism must enable the competent authority to tell a potential notifier whether its new chemical is on the inventory.

The Notification "Trigger"

Much has been made of the difference between pre-manufacturing and pre-marketing notification (U.S. vs EEC). The assumption has been that pre-manufacturing notification is more stringent as it reaches an earlier time in the new chemical development process. This is not necessarily true if a manufacturer has research, small quantity or test-marketing exemptions available to it. However, even such exemptions may have minimal notification requirements contingent on them. Most systems are also pre-importing notification schemes although importing is often included in the definitions of "manufacturer" or "placing on the market". A common failure in legislation is the lack of precision as to what is "importing" and which legal entity involved in the importing transaction is the responsible "importer". Some systems require a separate notification to customs authorities upon entry. The EEC system exempts chemicals in transit under customs control. This alleviates the legislative problem of giving notice 45 days before importing which would otherwise require notification long before a chemical shipment has left the exporting country.

Exemptions

Another significant characteristic is the number and extent of notification exemptions. Research, test-marketing, export, small quantity, byproducts, impurities, intermediates, polymers, previous notification are either reasons for exempting chemicals or are specific classes of exempt chemicals. Total exemptions do not require any information to be submitted whereas partial exemptions do require some identifying information to be supplied - this allows for "tracking" and subsequent action by regulation if hazard potential changes. Some exemptions are a matter of right, others must be applied for. Although related to total/partial exemptions, there is the distinction to be made between a notification exemption and a testing exemption.

Time Constraints

Requiring notification to be made prior to manufacturing/importing/marketing (eg: 45 days EEC, 90 days U.S.) puts a time constraint on industry as the notifier must be organized to submit all necessary data to the government to "start the clock running" so that contractual delivery commitments may be met. As well, in systems where a notifier is free to commence activity unless government disapproval is expressed within the time period, the notification authority is under a time constraint in its evaluation. Where express approval must be obtained from the government (usually in the case of permit/licence systems set up under poison trade laws) industry is less free and may wait an undetermined length of time unless the legislation requires a response from regulators within a specified time period. Where a system allows a time period for public review and comment and/or government response to those comments (eg: Netherlands) further time periods may be built into the system. The Australian interim system allows for an expedited review period of 7 days. Consideration must be given to justification for expedition in such case.

Content of Notification and Testing

The format of submitted material varies from the flexible format of the EEC to the printed form which must be filled out, with attachments, under TSCA. Where material is transmitted to other authorities (EEC), a summary is required. Under the Sixth Amendment specific categories of data must be given, such as identity, physico-chemical data,

toxicological and ecotoxicological test results and precautionary/emergency measures. A more detailed test program is arranged where quantities marketed reach certain levels. In distinction, the U.S. system requires the chemical identity but does not require specific tests to be done. However, the distinction is not particularly persuasive as categories of data and results which are listed are presumably "reasonably obtainable". If EPA is not satisfied with information supplied it can request further data and back up the request with prohibitions, although the simple lack of data is not enough justification for these actions.

Follow-up Action

One of the purposes of notification systems is to enable regulators to "track" new chemicals. While it is possible to require annual reporting on chemicals, this is not done, probably for the burden it would impose on everyone. Subsequent reporting has degrees of discretion. One possible requirement is for a notifier to supply further data when hazard assessment changes. This type of provision is broad and may result in regulators taking action after injury has occurred - which is contrary to the philosophy of modern chemical control. An alternative is to place specific "triggers" in legislation, such as the EEC requirement for data when certain quantities are reached. Quantity "triggers" are the most "fair" as the increase in quantity marketed means further testing is less of a cost burden. Another important trigger is a change in the composition of a chemical product, although many such changes would be innocuous. A discretionary "trigger", such as notification when new knowledge of a chemical's effects ought to come to a notifier's attention is important but on the face of it, lacks "teeth". A common "trigger" is when a chemical is subject to a new use. The latter is not easily identified. A significant consideration in any scheme is whether the onus is on a notifier to recognize when further data should be submitted or whether the onus is on the regulator to issue a rule specifying when data is to be submitted. TSCA is rule-oriented. After initial notification, EPA can issue a rule regarding a selected group of chemicals (s. 8(a) rule) or issue a SNUR (s. 5(a)(2) rule), both requiring follow-up data. One characteristic of the EEC system is that it is "open-ended" in that a new chemical doesn't become "old" but is notified for at least 10 years after its initial notification. This automatically allows "tracking" of changes in composition, effects, quantities and uses. A regulator need only compare submitted material with previous dossiers on file.

Special Orders

It is a characteristic of the permit/licencing systems for regulating the poison trade that conditions are imposed on marketing, use, etc. In distinction, the EEC does contain provision for labelling and packaging requirements but there is little flexibility for imposing special conditions on notified chemicals. This is because one of the purposes of the EEC system is harmonization and a reduction in non-tariff trade barriers. The U.S. system is similar to the EEC system in that approval is not given to notifications but differs in that conditions may be imposed - however, they are done through the issuance of specific rules. Most of the "special orders" in existence actually relate to orders requiring more information rather than the imposition of conditions and restrictions aimed at specific new chemicals. In most countries with modern notification systems, the ability to impose such conditions seems extraneous to the actual notifiction system in that the authority may come from another statutes or may come from a broad authority to issue specific regulations or orders. The question arises whether many countries have hesitated to tie the broad discretionary powers to impose specific condition to notification schemes because of anticipated reactions from industry and trading partners.

Confidentiality

Almost all countries have developed clear procedures to protect confidential data. Ironically, some countries which do not, are countries where there seems to be inherent secrecy attached to government activities (Japan, Yugoslavia). Confidentiality is demanded by industry and the greater the co-operation from industry required by a system, the more precise are confidentiality provisions. However, the more stringent confidentiality provisions are, the less the policy objective of public confidence and participation can be achieved. The Netherlands system is the most creative resolution of these choices. Lists of non-confidential data are common. No system specifically states the government is the "trustee" of submitted data as opposed to the "owner". In fact, many systems specifically state that government regulators have the last word on confidentiality -allowing notifiers to withdraw notification if they disagree. Most systems require notifiers to request confidentiality for specific data. This has resulted in a minimal amount of public information in the case of TSCA. The EEC has special confidentiality provisions because of the requirement that countries accept notification made in other Member States, and the role of the EEC Commission.

Offences and Penalties

This is one area in which there is dramatic variability. Fines and imprisonment range from the non-existent through the minimal (where a fine is a "licence to pollute") to the draconic. Distinctions are frequently made between negligent and criminal acts, and penalties apply accordingly. Many notification systems adopt enforcement and penalty provisions from other national legislation.

SUMMARY

of Notification Requirements in New Chemicals Legislation in EEC Member States

by

Peter Strahlendorf

Prepared under contract to the Commercial Chemicals Branch, Environmental Protection Service, Environment Canada.

June 20, 1984

Box 625, Stn. Q
Toronto, M4T 2N4
(416) 481-7088

SUMMARY
of Notification Requirements in New Chemicals Legislation in EEC Member States

The following is a nation-by-nation summary of the implementation of the Sixth Amendment in EEC Member States. The summary emphasizes the differences rather than the similarities in implementation efforts. In other words, one may assume that the national legislation provides for a 45 day notice review period as required by the Sixth Amendment, unless otherwise stated.

Belgium

Royal Decree No. 82-1000 came into force on July 2, 1982. It follows closely the Sixth Amendment. Pre-marketing and pre-importing notification are required but the important terms "manufacturer" and "importer" are not defined. An interministerial Commission of Dangerous Products evaluates submissions and must report to the Minister within 40 days of receipt. Chemicals excluded are the usual ones (eg: food, feedstuffs, medicines, narcotics) except they will be included in the notification system if they are not exclusively destined to be utilized as food, feedstuffs, etc. Thus, the Belgian net is potentially wide. Exemptions from notification are those indicated in the Sixth Amendment. However, the exemption for chemicals already notified in another EEC Member State is not as clearly stated as it might be. As well, the exemption is not clearly contingent on the other Member State having implemented the Sixth Amendment, so a potential loophole in the case of Greece is created. The Belgian system relies on the EEC inventory to distinguish notifiable from non-notifiable chemicals, but there is also a Belgian dangerous substances list. The data package required is the standard one and includes reference to a resume or abstract of the material. The MAD principle is expressly stated but the procedures for transmitting material to other Member States is not. The further testing required when quantities marketed reach certain levels does not refer to the 100/500 tonne levels as required by Annex VII of the Sixth Amendment. The "triggers" which require further data submissions (quantity, new knowledge, new uses, change in composition) are the standard ones. The quantity "trigger" does include the 100/500 tonne levels. No special orders regarding conditions and restrictions are evident. Full confidentiality provisions are given, including the list of non-confidential data. One difference is that a notifier must get permission to disclose data the notifier has requested to be confidential. Does this imply the government is the "owner" of submitted data? There is express permission to encode the identity of a chemical in the inventory unless it is classified as "dangerous". Results from studies done for previous notifications may be submitted but there is no requirement for written agreement for such use between notifiers. There is no provision for public participation. Violations are enforced under a 1921 statute (does this man penalties will be light?). Documented infractions are considered valid until proven invalid (an uncommon "reverse onus" clause).

Denmark

The Sixth Amendment was implemented by the Chemical Substances and Product Act and Order No. 409, both of which came into force on October 1, 1980. There is a parallel new

chemicals notification scheme in existence under occupational health and safety legislation. The Danish system is more stringent than the Sixth Amendment as a chemical must be notified if it is new to the Danish market, not just new to the EEC market. This violation of the Sixth Amendment may go to the European Court. It is also more stringent in that some existing chemicals must be notified. The scheme expressly applies to the export of new chemicals if manufactured in Denmark. Also unusual is the authority given to the competent Minister to include biotechnology products under the notification scheme. The usual exclusions are noted, except for narcotics and radioactive substances - are they impliedly included? The usual testing exemption is not stated. Instead, there is a total exemption for the resale of a notified chemical. The EEC exemption is contingent on an importer submitting a declaration that the chemical has been duly notified in another Member State. Denmark has its own inventory of chemicals on the Danish market before October 1, 1980 but provision for that inventory or for the EEC inventory is not expressly set out. Notification to NAEP is done by a special notification form. The base data package is equivalent to Annex VII but there is no reference to a "technical dossier", "declaration" or "summary" as in the usual format. Data otherwise required may be excluded for "technical or professional reasons", with justification. Existing chemicals (pre-October 1, 1980) require notification if they are sold or imported for "significantly" altered purposes or in increased quantities. Specific "triggers" for subsequent data submissions are phrased broadly as "significant alterations in or additions to previously filed information". Annex VIII testing requirements are implied. Broad powers are available to ban or restrict the sale, import or use of a hazardous chemical. Confidentiality provisions exist but a list of non-confidential data is not given. Proof of the agreement of previous notifiers is required for use of previously submitted data. Rules made pursuant to the legislation require input from industry, labour and consumer organizations. Fines are provided for but amounts are not stated. Imprisonment for violations may be up to 1 year.

France

Final implementation of the Sixth Amendment occurred through an October 21, 1982 amendment to the Chemical Control Law, although the major elements of the notification system were in effect by a supplementary Decree July 1, 1979. A parallel notification system operates under the Safety at Work Law. Importing is included in the definition of "marketing", but "importer" is not defined. Excluded chemicals are the standard ones. There does not appear to be a clear statement of the usual testing and research exemptions. Inventory, data package and testing requirements are not unusual. There is not an express reference to transmittal of data to other Member States. Quantity, new use and new knowledge "triggers" for subsequent notification are clearly stated. In addition there are broad powers to request further data on quantity, use and effects. Confidentiality provisions exist, as does a list of non-confidential data. Further rules are contemplated which will outline public access to non-confidential data; no other public participation is referred to. There is no provision for the written agreement of previous notifiers for the subsequent use of the previously submitted data. Maximum imprisonment for violations is up to 2 years. Fines range up to 500,000 Frs.

Germany

Implementation of the Sixth Amendment was by way of the Chemicals Act which became effective January 1, 1982. The scheme is one of pre-marketing and pre-importing notification but the actual terminology "keeping on hand for the purpose of selling or disposing of in other ways" has a broader meaning than marketing. A manufacturer must give pre-exporting notification if initial circulation will be in another Member State. The

definition of manufacturer is also broad and may include those who "obtain" a chemical. Importers must be "domiciled" in the EEC. Chemicals included in the scheme are substances as such or in preparations, and "substance" includes impurities or necessary additives. Existing chemicals, if "dangerous", may be notifiable. Excluded chemicals are those in the usual categories. As well, the usual exemptions apply, but in addition, terminology is such that there is a "non-commercial exemption" and an "on-site exemption" (for intermediates). Chemicals marketed pre-September 18, 1981 in the EEC are listed in a German Ordinance. Perhaps it will be updated with the anticipated 1985 release of the EINECS inventory. The submitted data package is not unusual. The MAD principle is applied and there is provision for data transmittal to other Member States but only if such states have confidentiality measures in effect. The notifier is consulted prior to transmittal. Data may be omitted if "technically impossible or unnecessary in view of the state-of-the-art of scientific knowledge". Further testing may be required at the 100/500 and 1000/5000 tonne levels of marketed chemical. Interestingly, the "ten year exemption" is subject to testing at the latter quantity levels. The usual use, quantity, new knowledge and change in composition "triggers" exist. In addition, notifiers must inform the government of quantities marketed every year (annual reporting) as well as indicate if marketing has ceased. Preconditions (unspecified) on marketing a chemical may be imposed if there are "real indications" of a potential danger. By ordinance, "dangerous" chemicals may be regulated. Confidentiality provisions include a list of non-confidential data. Written consent of a previous notifier is required if previous data is to be used. An administrative offence may bring a fine up to 100,000 Dm. A more serious "criminal" offence may bring a fine or imprisonment up to 5 years.

Greece

As of early 1983 there was a draft Presidential Decree which, when passed, would implement the Sixth Amendment, but there is no indication in the international literature that final action has been taken.

Ireland

The Notification Regulations came into effect on September 1, 1982. They follow the Sixth Amendment so closely that many of the latter's provisions, particularly definitions, are simply adopted by reference. Pre-marketing and pre-importing notification is given to an office of the Dept. of Labour by "manufacturers" and "importers" (terms undefined). Chemicals excluded are the usual. Notifiable substances in preparations are included. There is no clear EEC exemption although there is a vague provision which might imply it. The other exemptions are standard. The data package requirement follows closely the wording of the Sixth Amendment. The MAD principle is not clearly stated. Annex VIII test results shall be reported to the competent authority, which is a mis-application of the Sixth Amendment as the Annex VIII are to be applied in a flexible manner. The standard "triggers" for subsequent reporting are stated. The competent authority may, if necessary, ask for further data, test results and samples. "Appropriate measures (may be taken) relating to the safe use of a substance pending the introduction of Community provisions". The normal confidentiality provisions apply, and there is the usual list of non-confidential data. Consent in writing of previous notifiers is required for subsequent use of previous data. There is no provision for public participation. The possible penalty for an offence is only 600 pounds; a jail term is not mentioned. Commentators have noted the low penalty and the lack of a toxicology infrastructure as reasons for suggesting Ireland may be an "easy gatekeeper" to the EEC.

Italy

President Decree No. 927 implemented the Sixth Amendment. The Decree was issued on November 24, 1981, but officially published February 20, 1982. The Decree amends a prior Law No. 256 and some relevant definitions may be contained in the latter. The Decree follows closely the Sixth Amendment. Annexes I and II of the Decree appear to reproduce Annexes VII and VIII of the Sixth Amendment. The Ministry of Health receives the data package but it is evaluated by an interministerial Consultant Commission. The system requires pre-marketing and pre-importing notification although "introduction to the market" means a more far-reaching "delivery or disposal to others". Excluded chemicals are the usual except for a peculiar reference to "substances in which the container dissolves by itself". A notifiable substance in a product is included in the scheme. The exemptions referred to in the Decree are the standard ones. There is no evidence of an independent Italian inventory. There is nothing unusual in the provisions relating to the data package or to the testing requirements. Testing must be done at laboratories authorized by the Ministry. The MAD principle is applied in the case of EEC Member States. Express provision is made for data transmittal to the EEC Commission and other Member States and the Ministry may add its own comments to the notification material. Transmittal is not clearly contingent on other Member Sates having implemented the Sixth Amendment or having confidentiality measures in effect. The Decree itself does not contain a reference to the quantity levels requiring Annex VIII testing, but they may be contained in the untranslated Annex II. The standard new use, new knowledge and change in properties "triggers" are expressly stated. Where necessary, additional data and test results (from Annex II) may be requested, samples may be taken and the Ministry may "take necessary steps relative to safe usage" pending EEC Directives. The usual confidentiality provisions, including a list of non-confidential data, are expressed. The provision allowing previous "notification" to be used is unclear. There is not a clear requirement for written consent of an initial notifier for subsequent use of the previously submitted data. There is no provision for public participation. Penalty provisions are not in the Decree, although they may be contained in Law No. 256.

Luxembourg

A Bill has been drafted which, when enacted, will implement the Sixth Amendment. It is not known if a final Act has been passed. The crude translation of the Bill available indicates a close tracking of the wording of the Sixth Amendment. It is proposed that administration and notification evaluation be split between three Ministries. However, a separate 1982 Regulation creates a single Interministerial Committee to receive notification material. One interesting provision in the requirement is that every importer of a dangerous substance must be in possession of a certificate from the government of the exporting country certifying that the dangerous substance conforms with the exporter's national legislation. This requirement does not apply to EEC Member States. Fines for a first offence are up to 250,000 francs. Imprisonment may be up to one month. A second offence may bring a fine up to 500,000 francs.

Netherlands

The Sixth Amendment is to be implemented as the Chemical Substances Act, but it is not known if the available Bill has been finally enacted. There is to be a second law implementing the Sixth Amendment with respect to the working population. A voluntary interim notification scheme has been in effect since September 18, 1981. The interim Decree adopts by reference the main provisions of the Sixth Amendment. Notifications may

be made in Dutch, French, German or English. The notification authority is required to inform a notifier if submitted material is satisfactory, and if a confidentiality claim is justified, within 30 days of receipt. Non-confidential material is published and the public may obtain a copy. If passed as it stands, the Bill would be a pre-marketing, pre-importing notification system and, to some extent, a pre-manufacturing scheme - although "manufacturing" means producing "in order to put into circulation". The data package requirements are not in the Bill but will be set out by Order. Testing is not required if the notifier can "obtain the required data in some other way". Non-resident importers must appoint a resident agent to notify. The 30 day period for a response as noted above is continued. The 45 day review period may be extended to 5 months for pre-manufacturing notification by Order. Various provisions establish a system for public review of non-confidential data, comments may be submitted by the public, and the government must respond with reasons. Public information is recorded in a public register. The Annex VIII tests are not specifically referred to but step sequence testing is provided for. Exemptions appear to be more limited and are worded differently from the Sixth Amendment. Broad investigative and enforcement powers are provided for. The Bill contemplates an eventual permit system as well as a "superfund" mechanism. In summary, the Netherlands system is more complex, original and, perhaps more uncertain than the implementing legislation of other Member States.

United Kingdom

New Substances Regulations came into operation on November 26, 1982 with a transitional provision which ended in April 11, 1983. The Regulations are accompanied by 4 guideline booklets (GLP, and methods for determining physico-chemical properties, toxicity and ecotoxicity). A "pre-supply" notification system is actually a pre-marketing/pre-importing system, but may also be a pre-exporting system given the broad definition of "supply". Excluded chemicals cover most of the usual categories. "Substance" includes necessary additives. The usual total exemptions are provided for. In addition, an on-site intermediate would be exempt, not being subject to an act of "supply". The standard partial exemptions are also included in the scheme but the data supplied under the partial exemptions is not provided to other Member States. There is nothing unusual in the provisions for the data package, inventory or testing requirements. The MAD principle is covered by procedures for data transmittal by the Health and Safety Executive to other Member States but transmittal is expressly contingent on confidentiality measures being in effect. New use, and changes in properties and quantity are "triggers" for further data submission. A broadly worded provision states that notice must be given of "any other information" which becomes available which might reasonably be expected to affect the interpretation of any information previously provided. Schedule 5 reproduces the requirements of Annex VIII and the Executive must consider the need for further testing when the usual specified quantities of marketed chemical are reached. The Executive must balance a number of factors such as the quantity supplied, intended use, cost of testing, time required to carry out the tests, and must be satisfied further tests are "reasonably required" before ordering them. While there is a requirement for the protection of received confidential data, the Executive may submit data to other government entities or to outside specialists. In such a case other precautionary measures (eg: written undertakings) are used to protect confidentiality. A list of non-confidential data is stated. Previous notifiers must provide written consent to their data being used by others in subsequent notifications. There is no provision for public participation. Enforcement and penalties are provided for by the Health and Safety at Work Act although importation contraventions are dealt with under customs legislation.

SUMMARY
of Notification Requirements in New Chemicals Legislation in non-EEC OECD Member States

by

Peter Strahlendorf

Prepared under contract to the Commercial Chemicals Branch, Environmental Protection Service, Environment Canada.

June 25, 1984

Box 625, Stn. Q
Toronto, M4T 2N4
(416) 481-7088

SUMMARY
of Notification Requirements in New Chemicals Legislation in non-EEC OECD Member States

The following is a nation-by-nation summary of legislation, in effect in non-EEC OECD Member States, which requires notification of new chemicals. Some nations have legislation which is only peripherally of interest as their purpose is to regulate trade in recognized "poisons", not new chemicals generally.

Australia

A mandatory national chemicals notification and assessment scheme has recently been proposed for introduction during 1985. The scheme will be implemented by a system of complementary State and federal legislation. The scheme will require pre-manufacturing and pre-importing notification 90 days before introduction. There will be one national "notification authority" which will forward completed dossiers to various competent "assessment authorities", who will make recommendations to "control authorities". Details of this system are not available. An Australian inventory is being prepared listing existing (pre-January 1, 1984) chemicals. A chemical not on the list will be "new" and notifiable until 5 years have passed from the date of the first notification, at which point the chemical is added to the inventory. Negotiations are apparently going on with respect to coverage of chemicals already regulated (eg: agricultural chemicals). Special rules will apply to polymers. There will be a total exemption from notification for reaction intermediates and R & D chemicals below 100 kg. per annum. There will be limited notification for chemicals below 1 tonne/year, site-limited chemicals (below 10 tonnes/year) and R & D chemicals (more than 100 kg & below 1 tonne/year). The scheme may apply to biotechnology products with the broad definition of "UVCB". The scheme will also apply to existing chemicals if they have been designated for assessment. The notification dossier's content is similar to the OECD MPD .... changes may be made only if scientifically justifiable. Secondary notification is required if there is a significant new use or quantity increase (also thresholds of 10, 100, 1,000, and 10,000 tonnes/years), new knowledge, local manufacture, greater exposure likely or there is a change in composition. There will be provision for confidentiality claims for data other than items cited by OECD as non-confidential. Subsequent notifiers must certify they have the right to use any data submitted.

Austria

The Chemicals Law was enacted in 1982. It was modelled after the German legislation. A copy is not readily available. Commentators have reported that it is a pre-marketing/pre-importing scheme similar to the Sixth Amendment. It is known that excluded chemicals are those normally excluded under the Sixth Amendment. An Inventory of Existing Substances is to be compiled. A chemical not on the list will be new and notifiable. The data package appears to be the EEC base set (Annex VII) of tests. Further tests will be required if certain quantities are reached in the market. Unspecified powers to limit or prohibit the manufacture, marketing or use of a recognized dangerous substance are provided for. No other substantive information on the scheme is readily available.

Finland

From the information readily available, it appears that Finland has not developed a modern new chemicals notification scheme. Decree No. 286 of 1978 is concerned with substances hazardous to health in the occupational environment. Information is to be supplied to the recipients of the substances and the data package includes data on pertinent physico-chemical properties, health hazards and precautionary measures. There is no express provision for testing or submission of data to the government. A list of 1180 substances considered hazardous has been prepared by the government. Ordinance No. 492 of 1980 requires submission of toxicological and environmental test results with an application to import or manufacture "poisons" used in the wood industry. Limited data is supplied to customs authorities when importing poisons but no general notification scheme is evident under the Ordinance. The Ordinance does set up a licence system for importers and manufacturers of poisons generally and one would expect this scheme to include notification of data but the details are not readily available.

Iceland

There is no evidence that Iceland has established a notification scheme for new chemicals. Law No. 85 of 1968 regulates trade in poisonous substances. A licencing system is established. Presumably this would require some data to be submitted to the government.

Japan

The Chemical Substances Control Law of 1973 requires pre-manufacturing and pre-importing notification for new chemicals. There is also a notification requirement for hazardous "designated substances". A parallel notification system is operated under occupational health and safety legislation. Chemicals included in the scheme are elements, compounds and, impliedly, mixtures. Excluded chemicals include radioactive substances, specified poisons, stimulants and narcotics. Notifiable chemicals are "new", being chemicals not already approved, "designated substances" or chemicals on the List of Existing Chemicals. Notification is submitted to MHW and MITI and the government has 3 months to decide if the chemical is safe (approval), hazardous (disapproval), or if it is not clear. Notification is not required for reagents or for chemicals used for testing and research purposes. Orders may be issued exempting chemicals if they are "intermediates of medical supply" and chemicals in quantities less than 100 kg/year, but in these cases some data must be submitted. Special documentation procedures apply to imported new chemicals. The data package includes information on physico-chemical properties, use and quantities as well as other unspecified information which will assist MHW and MITI in their decision whether the chemical is safe or hazardous. Evaluation is a two-step process. Based on available information, an initial decision is made whether the chemical is biodegradable, bioaccumulative or harmful to health. If it is not clear, further toxicity and ecotoxicity tests are done, although it is not clear how the testing is shared between the government and the notifier. In practice, chemicals are submitted for prenotification tests. A chemical is normally withdrawn and formal notification is not yet made if the tests reveal a hazard potential. There is no indication of the application of the MAD principle. Once a chemical is approved as safe, there does not appear to be further testing requirements. If a substance is hazardous, it becomes a designated substance and extensive provisions apply to its regulation. If a non-designated substance is suspected of being hazardous, various restrictions may be placed on the manufacture, import or use of the substance. General provisions cover on-going reporting of business activities. The names of safe chemicals are published but otherwise there is no reference to public disclosure or public participation in

the system. Penalties for notification violations are fines up to 100,000 yen and/or imprisonment up to 1 year.

New Zealand

The Toxic Substances Act 1979 regulates trade in toxic substances; it is not a new chemicals notification system per se. It is a pre-importing, pre-manufacturing and pre-packaging notification scheme for toxic substances. Notification is given prior to those acts but a specific review time period is not indicated. Chemicals included in the definition are substances defined by Order as "deadly", "dangerous" or "harmful" substances, "standard poisons", pesticides or other substances which may adversely affect the environment. The notification scheme does not apply to tobacco, food, drugs or radioactive material, as well as registered pesticides or substances used in laboratory research. Notification is required if the toxic substance is "new" to the prospective notifier, not "new" to the market. An inventory is not provided as it is presumably not needed. The data package includes information on composition, purpose and method of use and "other particulars" as may be required. There are no mandatory testing requirements. Following notification, further sale, quantity and identity data may be requested of any person involved in toxic substance trade. Broad powers are given to impose such conditions, as the Minister of Health thinks fit, on the trading in any toxic substance. Confidentiality provisions apply. There is no mention of public participation in the system. Violations may result in imprisonment up to 3 months or $500 ($50/day if the offence continues).

Norway

Under the 1976 Product Control Act and the 1982 Regulation No. 1635 the Norwegian system has, as its central elements, a classification scheme, a Product Register and a permit system. A special notification requirement exists for suspected carcinogens whether they are new or existing chemicals. Notification is required for the manufacture or import of the more hazardous classes of chemicals. Notification is impliedly required before such acts occur, although a specific time period is not given. The scheme does not distinguish between new or existing chemicals. Manufacturers and importers are required to classify substances by comparing the properties of their substances with those on a published Product Register. They are required to obtain such knowledge as is necessary to do so. If they determine that their substance is in the class of "very toxic" or "toxic" or if they suspect it is carcinogenic, then it is a notifiable substance. There is a specific mechanism available to classify mixtures. Excluded from the scheme are most manufactured articles, alcohol, food, pesticides, medicine, tobacco and feedstuffs. Quantities less than 100 kg/year are exempt. Other exemptions may be made on a case-by-case basis. The data package is minimal, containing primarily identification data and classification. There are no specific mandatory testing requirements. The MAD principle is not recognized. Notification must be given if the quantity, area of use or composition of a substance is substantially altered. Wholesalers must submit a notification every two years. Temporary bans may be imposed on trade until sufficient information is supplied. Confidentiality provisions exist. Public participation is not mentioned. Fines (unspecified) and imprisonment up to 2 years may be imposed.

Portugal

There is no indication that Portugal has drafted or enacted legislation relating to new chemical notification.

Spain

There is no indication that Spain has drafted or enacted legislation relating to new chemical notification.

Sweden

Act No. 329 and Ordinance No. 334, both of 1973, establish a general notification scheme for "poisons" and "dangerous substances" which are manufactured or imported. There is no express reference to notification of new chemicals. But as the government may intervene on a suspicion that a substance is harmful, a manufacturer or importer is likely motivated to request the Products Control Board to issue a ruling whether a substance is hazardous. The system does not cover food, drugs, feedstuffs, radioactive substances and some flammable or explosive products. Details are not available as to specific data required under this scheme. There is no specific mandatory testing. There are two 1979 Ordinances which require notification for a specified list of chemical products derived from the Swedish Customs Tariff. This is a notification regarding trade in existing substances. The Swedish legislation is undergoing review and will likely be amended shortly.

Switzerland

The 1979 Toxicity Law regulates trade in toxic substances. Any toxic substance entering the market must first be reported to the government for classification. A toxic substance may not be marketed until it has been included on the List of Toxic Substances. This must be decided upon within two months. The system is a form of pre-marketing notification, although marketing is so broadly defined that it includes initial manufacturing. Subsequent to notification, classification and listing, a permit is required before trade can commence. Notifiers must be domiciled in Switzerland. Chemicals excluded are radioactive substances, drugs, food and consumer goods. "Substance" includes simple mixtures. "Toxic substance" is defined very generally. There are exemptions for research, intermediates and toll manufacturing. To be entered on the List of Toxic Substances a data package must be submitted containing test certificates regarding the toxicity or degree of hazard of the chemical. Specific mandatory tests are not stated. However, classification is based on "overall hazard" and it is stated that acute oral, sub-acute, chronic and absorption studies contribute to the evaluation. Permits may be issued subject to conditions. Additional tests may be specified in some cases. Confidentiality provisions exist. Certain minimal categories are published in the List of Toxic Substances. As well, some data is provided to Toxicology Information Centres. Penalties are fines up to 20,000 francs and/or 6 months imprisonment. If an offense results in an "unlawful precuniary advantage", the "culprit (must) pay an equivalent sum to the State".

Turkey

There is no indication that Turkey has drafted or enacted legislation relating to new chemical notification.

United States

The Toxic Substances Control Act of 1976 establishes a pre-manufacturing/pre-importing notification scheme whereby notification is submitted to the EPA 90 days before a new

chemical is manufactured or imported for commercial purposes. Excluded are mixtures, pesticides, tobacco, nuclear material, firearms, food and food additives, drugs, cosmetics and devices. Notifiable chemicals are new chemicals not being on the Chemical Substance Inventory, which is continuously updated. Totally exempt are chemicals for research or export and certain byproducts, impurities, non-isolated intermediates and coincidentally produced chemicals. A person may apply 45 days in advance for a test-marketing exemption but some information must be provided and restrictions may be imposed. EPA may issue a rule exempting a chemical if it will not present an unreasonable risk. Exemptions are proposed for site-limited intermediates, polymers and chemicals produced in small quantities but these exemptions will require some advance notification. The data package requires submission of chemical identity but all other information is not mandatory. Categories of requested data are listed under three parts: 1) general commercial information; 2) human exposure and environmental release; and 3) attachments such as risk assessments, assessment of ultimate environmental fate, test results, hazard warnings, etc. Information is required to be submitted if it is "known or reasonably ascertainable". There is no specific obligation to conduct tests to generate data. If submitted material is incomplete, the notice review period may be extended for another 90 days. If new information is obtained during the review period it must be submitted. The OECD MPD is recommended as a guideline as to what test data should be generated. During the review period EPA may issue orders barring or restricting manufacture or import of a substance which may present an unreasonable risk. After the review period EPA may issue a SNUR or Follow-up Reporting Rule to keep track of existing and new chemicals on the market. If EPA does not disapprove of a notification after 90 days or extend the review period then a notifier may commence activity following submission of a notice of commencement of manufacture. A notifier must claim confidentiality for each item of information submitted. Other than a confidentiality claim for chemical identity a claim need not be substantiated. Generic names and uses may be submitted in the "sanitized" PMN forming part of the public record. A notice is published in the Federal Register upon receipt of a PMN. An FOIA application will prompt a review of a notifier's claim for confidentiality. Fines up to $25,000 and imprisonment up to 1 year may be imposed for violations.

Yugoslavia

The Poisons Trade Act and its Regulations both of 1982, require that poisons be classified before marketing or use. The application for classification may be thought of as notification. As well, the legislation requires post-manufacturing and post-marketing notification. Only "organizations of associated labour" are permitted to trade in poisons. The system is not directed at new chemicals. However, one must determine if a new chemical is a poison. A "toxicological evaluation" is performed by an independent organization of associated labour and this is submitted with the application for classification. The testing requirements are similar to Annex VII tests of the Sixth Amendment. There is no express provision for the MAD principle, flexibility in notification requirement, step sequence testing, the protection of confidential data or public participation. A variety of penalties may apply to violations.